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10/536,685	11/30/2005	Stefan Heckl	03528.0147.PC/US00	4627

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EXAMINER

JONES, DAMERON LEVEST

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1618

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DELIVERY MODE

10/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/536,685

Applicant(s)

HECKL ET AL.

Examiner

D L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-5, 7-9 and 22-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 7-9, and 22-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 7/26/10 wherein claims 2, 6, and 10-21 were canceled; claims 1, 3-5, and 7-9 were amended; and claims 22-31 were added. In addition, the Examiner acknowledges receipt of the acceptable terminal disclaimers.

Note: Claims 1, 3-5, 7-9, and 22-31 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. The Applicant's arguments and/or amendment filed 7/26/10 to the rejection of claims 1-11 and 17-21 made by the Examiner under 35 USC 112 and/or double patenting have been fully considered and deemed persuasive-in-part for the reasons set forth below.

Double Patenting Rejections

I. The double patenting rejection over US Patent Nos. 7,531,502; 7,563,761; and 6,821,948 are WITHDRAWN because Applicant submitted an acceptable terminal disclaimer.

II. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1, 5, and 9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-8, 11, 13-16, 19, and 21 of copending Application No. 12/634,972 is MAINTAINED. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a composition comprising a transport component (i.e., a peptide), a nuclear localization sequence module, and a signaling module. The claims differ in that the copending application does not specify that the

transport peptide is of human origin. However, the skilled artisan would recognize that the claims of the copending application encompasses those of the instant invention because the inventions disclose overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Note: It is duly noted that Applicant has requested that the rejection be held in abeyance until allowable subject matter is indicated in the instant invention.

Written Description Rejection

Applicant's Assertions

In summary, Applicant asserts that the rejection should be withdrawn on the basis that amphiphilic transport proteins of human origin are well known in the art. Thus, Applicant concludes that since cell penetrating peptides are well known in the art one can immediately envisage what class of compounds are comprised by amphiphilic transport peptides of human origin. In addition, Applicant asserts that nuclear localization sequences have a clear meaning in the art of nuclear localization sequences.

Examiner's Response

Applicant's arguments are non-persuasive for reasons of record in the office action mailed 3/25/10 and those set forth below. First, while amphiphilic transport proteins are penetrating peptides, one of ordinary skill in the art would not be able to readily envision what specific amphiphilic transport proteins of human origin Applicant is claiming that are compatible with the nuclear localization sequences, and signaling

modules combination Applicant is intending to be compatible with the instant invention. Thus, while both nuclear localization sequences and amphiphilic transport proteins are generally known in the art, the generic terms encompass a vast genus of compounds. Thus, the issue still remains whether or not the specification demonstrates that Applicant generated sufficient species to support a claim to such a genus. The issue is of particular concern when a genus claim uses functional language to define the boundaries of the claimed invention. In this particular instance, the functional language is directed to a desired result. However, Applicant is reminded that the specification must demonstrate that Applicant has made a generic invention that achieves the claimed result and do so by a showing that the Applicant has invented species sufficient to support a claim to the functionally defined genus. Likewise, in regards to Applicant's assertion that nuclear localization sequences are targeting signals and known in the art, it is noted that having a clear meaning as being a targeting signal is not the same as knowing what actual sequences are compatible with the instant invention. Thus, the rejection is deemed proper.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 3-5, 7-9, and newly added claims 22-31 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **MAINTAINED**. The claim(s) contains subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to the following: (1) what amphiphilic transport peptides of human origin Applicant is referring to that is compatible with the instant invention; (2) nuclear localization sequence or sequences are compatible with the instant invention; (3) what conjugate combination is compatible with the instant invention; and/or (4) what human homeobox protein HOX-B1 derivatives Applicant is referring to that are compatible with the instant invention and which derivatives are useful with various conjugate combinations; and (5) what combination of the components will yield the desired result. The claims encompass a genus of unspecified components (i.e., transport peptides, nuclear localization sequences, human homeobox protein derivatives, etc.). Review of the disclosure does not provide sufficient description of the various components. For example, on pages 5-6, the term 'derivative' sets forth that one or more of the amino acids in the homeobox protein is

substituted, deleted, or an addition(s) has occurred at one or multiple locations, but the disclose does not set for all possible combinations that are combinable with other components of the conjugates or possible combinations that have such modifications that yield the desired results. On page 6, lines 7-12, the transmembrane module is defined as being produced biologically. While the specification gives a few specific conjugate component combinations (see page 18, Table 1), the disclosure is not such that a skilled artisan would know what combination or even components are appropriate and useful with the instant invention. As a result, what the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description

requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

112 Second Paragraph Rejections

I. The 112 second paragraph rejections over claim 3 is WITHDRAWN because Applicant amended the claim to overcome the rejection.

II. The 112 second paragraph rejections over claims 3, 6, 10, and 17-21 are WITHDRAWN because the claims have been canceled.

III. The rejection over claims 1, 5, 7-9, and newly added claims 22-31 (see below) are MAINTAINED (see below).

Applicant's Assertions:

It is duly noted that asserts that amphiphilic transport peptides are known in the art.

Examiner's Response:

Applicant argument is non-persuasive because while an amphiphilic transport protein of human origin is characterized in that they penetrate the plasma membrane, it is unclear how what determines which specific peptides are compatible with the instant invention since the composition comprises the amphiphilic transport peptide, signal module, and nuclear localization sequence. Thus, the claims are vague and indefinite.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 7-9, and newly added claims 22-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5-9, and newly added claims 22-27: The claims as written is ambiguous because it is unclear what amphiphilic transport peptides of human origin Applicant is referring to that is compatible with the instant invention. Likewise it is unclear what nuclear localization sequence that may be used with the instant invention. Furthermore, the claim is ambiguous because it is unclear what conjugate combination is compatible with the instant invention. Specifically, it is unclear what components are necessary for each conjugate composition combination to be operable.

101 Rejection

The 101 rejection is WITHDRAWN because Applicant canceled claims 17-21.

COMMENTS/NOTES

3. Applicant is reminded that it has been held that the recitation that an element is 'capable of' performing a function is not a positive limitation, but only requires the ability to so perform that function. Thus, such terminology does not constitute a limitation in any patentable sense (In re Hutchison, 69 USPQ 138).

Note: The phrase 'capable of' appears in independent claim 1.

4. It should be noted that no prior art is cited against the instant invention. However, Applicant **MUST** address and overcome the double patenting and 112 rejections.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

September 29, 2010